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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,053	04/02/2004	Donald M. McDonald	UCSF-077CON7	2231

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,053	MCDONALD ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-26-04, 8-2-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims included in the prosecution are 1-18.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Felgner (5,264,618) of record.

Felgner discloses cationic lipid formulations containing steroid, hydrocortisone (note the abstract, columns 20 and 21, examples, example 12 in particular and claims).

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Folkman (5,837,682) of record.

Folkman discloses lipofectin-DNA complexes; the DNA sequence codes angiostatin (note the abstract and col. 39, line 4 et seq.).

4. Claims 13 and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Weichselbaum (5,770,581) or Weichselbaum (5,641,755).

Weichselbaum discloses compositions containing a promoter linked to DNA encoding angiogenesis inhibitor and cationic lipids (note the abstract, col. 4, line 1

through col. 5, line 67, col. 14, lines 52-65, col. 23, lines 63-67 and claim 4 in 581; abstract, col. 12, lines 45-46, col. 14 and claims).

1. Claims 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Felgner (PNAS, 1987) of record.

Felgner discloses Fluorescent labeled cationic lipid-DNA complexes (note col. 1 on page 7414).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (5,935,937) of record.

Smith while disclosing compositions containing antisense nucleotides for apoptosis suggests the use of liposome compositions containing cationic lipids and together with microtubule disrupting agent, paclitaxel (note the abstract, column 6, line 64 through col. 7, line 9 and example 9). It would have been therefore, obvious to one of ordinary skill in the art to formulate cationic liposome compositions containing paclitaxel with a reasonable expectation of success.

7. Claims 13, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weichselbaum (5,770,581) or Weichselbaum (5,641,755) by themselves or in combination with WO 93/24640 of record.

Weichselbaum does not teach that the angiogenic inhibitor to be an antisense-nucleotide, which disrupts the expression of DNA in angiogenic endothelial, cells. The use of a specific inhibitor in the teachings of Weichselbaum would have been obvious to one of ordinary skill in the art since one would expect at least similar results. One of ordinary skill in the art would be motivated to use an antisense-nucleotide sequence since the reference of WO shows incorporation of an antisense nucleotide to disrupt the expression of desired DNA in a specific cell type (note the abstract and page 24, lines 6-7).

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Folkman (5,837,682) or Felgner (5,264,618) or Weichselbaum 581 or 755 cited above, in combination with Felgner (PNAS, 1987) cited above.

The teachings of Folkman, Felgner, 618, Weichselbaum 581 and 755 have been discussed above. What is lacking in these references is the inclusion of a label in the compositions. Such an inclusion however, with a reasonable expectation of success in both detection and therapy since the reference of Felgner, PNAS shows that compositions can also be labeled.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-11 and 13-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,837,283. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims 1-10 are drawn to a method of selectively affecting angiogenic endothelial cells using a cationic lipid and angiogenic enhancers and angiogenic inhibitors whereas instant claims 1-11 are drawn to the same method using a substance, which affects angiogenesis. Since the patented claims define the substance, which affects the angiogenesis as an enhancer and an inhibitor, it is implicit that instant 'substance' encompasses both enhancer and inhibitor in the patented claims. Instant composition claims are included in the rejection since the patented method claims are practiced by the same composition and it would have been obvious to one of ordinary skill in the art that the specific substances claimed in instant

claims are included in the generic expression in the patented claims since said specific substances are known angiogenesis modifying substances.

11. Claims 13-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,120,799. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and instant claims are drawn to the same cationic liposome compositions; instant claim 13 is generic with respect to angiogenesis inhibitor and the dependent claims in said patent and instant application recite the same compounds and therefore it would have been obvious to one of ordinary skill in the art that instant 'inhibitor' encompasses the nucleotide sequence which encodes a protein recited in the claims of said patent.

12. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,756,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and instant claims are drawn to the same method using cationic liposome compositions; instant claims are generic with respect to the substance which affects the angiogenic endothelial cells whereas the patented claims recite steroids as the specific substances. It would have been obvious to one of ordinary skill in the art that any angiogenesis would behave the same way since it is the claimed cationic liposomes which have the property to selectively affect the endothelial cells and this property would remain the same irrespective of the substance within the liposomes.

13. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-31 and 33-37 of copending Application No. 10/302,374. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in instant application and the copending application are drawn to the same method of selectively affecting angiogenic endothelial cells. Claims in the copending application recite "allowing the liposomal composition to selectively associate with angiogenic endothelial cells of an angiogenic blood vessel for a time and in a manner such that the liposomal composition ***affects*** the angiogenic endothelial cells wherein the liposomal composition has greater affinity for angiogenic endothelial cells as compared to corresponding normal endothelial cells" whereas instant claims recite, "allowing the liposomal composition to selectively associate with angiogenic endothelial cells of an angiogenic blood vessel for a time and in a manner such that the liposomal composition ***enters*** the angiogenic endothelial cells". It would be obvious to one of ordinary skill in the art that since claimed method selectively affects the angiogenic endothelial cells, the composition would inherently have greater affinity for the angiogenic endothelial cells as recited in the claims of said copending application. Since if the angiogenesis process is affected, it would affect the blood supply instant claim 12 and the method of treatment of a disease associated with angiogenesis or tumor in claims 31 and 33-37 are deemed to be obvious. Instant composition claims are included since the method in copending application is practiced with the same composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-45 and 47-55 of copending Application No. 10/161,194. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in instant application and the copending application are drawn to the same method of selectively affecting angiogenic endothelial cells. The claims in copending application are drawn to specific cationic lipids and their amounts and the substance, which affects the angiogenesis, is a taxane whereas instant claims are generic with respect to the cationic lipids and the angiogenesis affecting substance. . It would have been obvious to one of ordinary skill in the art that any angiogenesis would behave the same way since it is the claimed cationic liposomes which have the property to selectively affect the endothelial cells and this property would remain the same irrespective of the substance within the liposomes. It would have been obvious to one of ordinary skill in the art to select specific cationic lipids and vary its amounts or the amounts of the substance, which affects angiogenesis with a reasonable expectation of success.

15. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

16. Claim 12 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of prior U.S. Patent No. 5,837,283. This is a double patenting rejection.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GSK

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK